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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,738	12/08/2000	William Peter Van Antwerp	G&C 130.9-US-U1	4789

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EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1653	12

DATE MAILED: 05/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/733,738	Applicant(s) VAN ANTWERP ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Pursuant to the directives of paper No. 11 (filed 3/3/03), claims 19 and 21 have been amended, and claims 1-18 cancelled. Claims 19-24 remain pending.

Applicants' arguments filed 3/3/03 have been considered and found persuasive in part. The rejection of claims 19-24 under 35 U.S.C. §112 second paragraph is withdrawn. The rejection of claims 19-21, 23-24 over Massey ('341) is also withdrawn.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 now recites that the "buffering molecule... mitigates the change in pH that results from the formation of carbonic acid". However, this language is not explicitly supported. The passage at page 5, lines 18-27 (specification) has been considered, but this does not support the phrase at issue. The passage at page 5, lines 18-27 makes reference to CO_2

per se, rather than the acid which results from hydration of CO_2.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 19-24 are rejected under 35 U.S.C. §103 as being unpatentable over Langballe (USP 6,174,856).

As indicated previously, Langballe discloses a method of stabilizing insulin. The solution may contain at least one buffer selected from Gly-Gly, Tris, and citrate. (See, e.g, col 3, line 52+; col 3, line 64+). Thus, for the chemist endeavoring to use more than one such buffer, there are three such possibilities: Gly-Gly and Tris, Tris and citrate, Gly-Gly and citrate. Also disclosed (col 5, line 64+) the use of an "additional buffer". Thus, there is motivation to use two different buffers. In addition, it is recited (col 5, line 66+)

that citrate can serve the role of a buffer or a zinc complexing agent. Furthermore, it is disclosed (col 6, line 29) that when zinc was used, it was added as the "acetate". Thus, a practioner might choose Tris in combination with citrate to complex the zinc, or the practioner might simply select Tris as the only buffer, but then use zinc acetate, thus meeting the requirement for the second buffer.

In response to the foregoing, applicants have argued that Langballe does not disclose a buffer system which comprises TRIS and citrate. Perhaps it is true that a rejection under 35 USC §102 would not be appropriate. However, the combination of TRIS and citrate is rendered obvious by the reference. Once in possession of the mixture comprising TRIS and citrate, the skilled artisan is then in possession of a "buffering molecule that mitigates the change in pH that results from the formation of carbonic acid". It is true that the reference also suggests, in another embodiment, a mixture which contains Gly-Gly. However, (a) the reference does not disclose that Gly-Gly is a requirement, and (b) the instant claims do not preclude Gly-Gly. As indicated above, the reference does not require Gly-Gly. For the chemist endeavoring to use more than one such buffer, there are three possibilities for a buffer: Gly-Gly and Tris, Tris and citrate, Gly-Gly and citrate. The ternary buffer system comprising Gly-Gly, Tris and citrate is also implied by the reference. Thus, the chemist who has selected the Tris and citrate would have met the requirements of the claims. But the chemist who has selected the ternary buffer system

comprising Gly-Gly, Tris and citrate would also have met the reqirements of the claims. The claims do not exclude buffers that bear a free amine group; all that can be said is that the claims do not require the presence of such a buffer.

Thus, the claims are rendered obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800